ATTN: **THE DOCKETS MANAGEMENT BRANCH**
FROM: **VINA RAMALINGAM – KUALA LUMPUR, MALAYSIA**
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Dear Sir/Madam,

What follows below are some comments on the proposed amendments to the Guidance Manual and other changes being proposed. I do hope the FDA looks very closely at all comments with respect to the new Proposals and takes actions, which are appropriate.

1. **1200 microgram limit per glove**

The assumption made by the FDA that a glove is only 6 grams is rather unrealistic. A beadless glove that is 240mm long with minimum thickness would be hard pushed to meet a 6-gram weight.
A thicker glove would intuitively provide better protection (re. EMS gloves), but due to this restrictive specification requested by the FDA require the producer to announce a very high protein content.
The original declaration suggested by the FDA last year was a based on the area of the glove rather than the weight. This seems to make more sense, as the tendency is that a heavier glove would produce lower readings.

To further complicate matters, it seems very likely that the FDA is requesting a limit that, firstly, is not achievable by the majority of manufacturers, is not going to be policed by the FDA and which requires a test method that is currently very much in doubt as to its accuracy or repeatability.
The cost to conscientious manufacturers to test, validate and document their systems to report "correct" numbers is going to come to nought if the majority of manufacturers are going to report a fictitious number in the first place. If this sounds far fetched, the FDA should test all the available powdered and powderfree gloves in market at the moment carrying protein claims.

The limit being suggested by the FDA does not seem to be supported by any data to show that this is a **"safe"** level. Furthermore it seems to contradict a report by Messrs.Turjanmaa, Yip et al in a report of a few years ago that suggested a level of less than 400micograms showed no significant problems to sensitized people.

2. Shelf Life

The requirement for declaration of shelf life of gloves is commendable but it must also follow with a protocol on the test method to be used to determine this. What is the point for any manufacturer to carry out long term test which is going to take a minimum of two years to complete, cost a small fortune, use up valuable time of personnel and resources, if the FDA in one fell swoop determines halfway down the line that the protocol to be used must be FDA approved or is not acceptable?

Would it not be a lot easier for the protocol to be drawn up and set prior to the execution of these tests?
There also exists a number of questions on these shelf life declarations. In the case of a chlorinated glove, does the clock start ticking at the point of manufacture of the powdered product or at the point of manufacture of the powderfree glove?

3. Recommended/Required limits on powder and protein levels.

Powder limits on p/free glove should be a required limit as it is has been the practice for the last few years and all manufacturers should be capable of meeting these levels already.

The protein levels for gloves should be a recommendation only and that the limit should be 400micrograms per gram or preferably a square decimetre. This recommendation is supported by the study referred to in section one in the previous page.

4. Exemptions

Provision to exempt selected manufacturers from the new rulings should not be allowed. This sounds like selective discrimination and there should not be any place for it.

5. **Alternative Powders**

There is already an alternative powder (Oat Starch) available (which has been tested by the Mayo clinic and a paper presented at the AAAAI show in Orlando earlier this year) that binds little or no protein. There are a number of ongoing tests being carried out by various organizations to determine the effectiveness of this powder.

The FDA's view that the growth of powderfree gloves is going to escalate in the next few years was the same theory put forward a few years ago and this has proven to be wrong.

6. **Powder Levels of 120mg per Glove.**

The use of this limit as with the use of the 1200 micrograms per glove level is very interesting from the point of view of a user. Is the FDA suggesting that a 120mg limit on powder is safe or is it merely better than 240mg or 360mg? This level would suggest that the FDA has studies to suggest this limit is, firstly achievable, secondly safe and thirdly adequate in allowing a user to put on a glove without stressing the glove more than he or she should?

7. **Reclassification of Exam Gloves as a Class II Device.**

The classification of this product as a Class II device and the additional controls it requires will undoubtedly increase the cost of the finished product. However, this will only be true for those manufacturers who follow the regulatory requirements. The FDA's audits of manufacturers to ensure that they follow GMP principles seem at the moment to be skewed a great deal. Enforcement of rules pertaining to manufacturers who are clearly breaking the regulatory requirements seem to be lacking and this is quite frustrating to genuine manufacturers.

What we have at the moment are a new set of rules that will not be enforceable by the FDA until and unless they audit **all** manufacturers. This has to be carried out at least once every two or three years by the FDA, or the FDA should use third party auditors, carried out (at FDA's cost) on manufacturers to even the playing field.

We have at this juncture, audacious tactics undertaken by manufacturers (who are on detention) like changing their company names and using one of many 510(k)'s they possess (look closely at the detention list and call up the Management reps for each company or check the company addresses). The FDA has stated that

detentions are based on **Management** of companies and not factory or 510(k) based. The reality though is that, it is 510(k) and factory based. The reclassification of the device as a Class II device is going to take this cat and mouse game, deeper into the realms of a "Catch me if you can" situation.

The cost of manufacturing a glove is going to go up, factory owners who can't **spell** GMP, let alone practice it, are going to sell gloves at a price far below what would be a realistic price. The rest of the manufacturers will have to compete with prices at these levels and barely break even. Buyers will not be willing to pay prices that are required to keep all these systems in place (and make a profit at the same time). Please understand that all these factories were started up to make a profit, not as charitable concerns. Yet the current situation is that most manufacturers in Malaysia are barely breaking even, because of price pressures. Are buyers going to pay more because the product just became a Class II device and the packaging states protein and powder levels and expiry dates? I very much doubt it.

Thank you very much for allowing me to comment on the proposed amendments. I do hope that these comments will be taken into consideration.

Best regards,

Vinayagan Ramalingam
28th October 1999